



ERREGIERRE S.p.A.

San Paolo d'Argon, July 14, 1999
Ns. Rif.:FL/sp

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm.
1016, Rockville, MD 20852

Re.: Proposed new ruling for Foreign Establishments

Dear Sirs,

We make reference to the notice in the U.S. Federal Register, vol. 64 No. 93, Friday, May 14, 1999 concerning Foreign Establishment Registration and Listing. On pages 26331 (definition of "United States Agent"), 26334 (bottom of first column and second column) and 26341 (second column, text proposed), it is reported that each foreign establishment will be allowed for only one U.S. agent rather than multiple agents as at the present.

This proposal, that at first seems to be logic and reasonable, can not actually be applied. In fact, each establishment has got its own list of products, some of which are often produced by others establishments too.

In this case, when the establishment A designates an US agent, it might occur that, for some of the products of its list, the agent is already engaged to represent the establishment B and thus it can not represent the establishment A for the same product, in order to avoid any eventual clash of interests. In fact, it is not possible that an agent represents two or more establishments for the same product.

At this point the establishment A should give up promoting and selling such a product in U.S., or it has to designate another agent.

It stands to reason that the first solution can not be applied, while the second one, that has been applied till now, seems to be the only one possible.

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It has to be reminded that in the DMF of each product, the name of the agent and its address, with whom FDA will communicate and interact for that product, are always indicated, so we do not see any limit to the possibility of FDA interaction even maintaining the present situation, that allows to an establishment to be represented by more than one agent.

In order to avoid great difficulties to the foreign establishments, that would be prevented to apply what proposed, we kindly ask you to consider what explained above and to reconfirm the present procedure that allows using more than one agent.

Thank you for the kind attention. We look forward to receiving your comments.

Best regards,

ERREGIERRE S.p.A.


Dr. Fiorella Lombardi
Regulatory Affairs Manager

AIRBILL NUMBER

E P 11 96 529912

PRODUCT

DOC

DISINTEGRATION

GA I



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1 OF 1
ORIGIN. BGY



KW KUWAIT
 KG KYRGYZSTAN
 LA LAOS/LAO PDR
 LV LATVIA
 LB LEBANON
 LS LESOTHO

MS MONTSERRA I
MA MOROCCO
MZ MOZAMBIQUE
MM MYANMAR
NA NAMIBIA

RW RWANDA
MP SAIPAN
ST SAO TOME AND
PRINCIPE

OF
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ND

SA SAUDI ARABIA
SN SENEGAL
SC SEYCHELLES
SL SIERRA LEONE
SG SINGAPORE
SK SLOVAKIA
SI SLOVENIA
SO SOMALIA
ZA SOUTH AFRICA
ES SPAIN
LK SRI LANKA
XY ST. BARTHELEMY
XE ST. EUSTASIUS
KN ST. KITTS
LC ST. LUCIA
XM ST. MAARTEN
VC ST. VINCENT
SD SUDAN
SR SURINAME
SZ SWAZILAND
SE SWEDEN
CH SWITZERLAND
SY SYRIA
PF TAHITI
TW TAIWAN
TJ TAJIKISTAN
TZ TANZANIA

TH THAILAND
TG TOGO
TO TONZA
TT TRINIDAD AND TOB
TN TUNISIA
TR TURKEY
TM TURK MENISTAN
TC TURKS AND CAICO
TV TIVULU
UG UGANDA
UA UKRAINE
AE UNITED ARAB EMIR
GB UNITED KINGDOM
US UNITED STATES OF
AMERICA
UY URUGUAY
JZ UZBEKISTAN
VU VANUATU
VE VENEZUELA
VN VIETNAM
VG VIRGIN ISLANDS (U
WS WESTERN SAMOA
YE YEMEN
YU NEW YUGOSLAVIA
ZR ZAIRE
ZW ZAMBIA
ZM ZIMBABWE

MESSAGE TO COURIERS: PLACE ANY SERVICE ALERT LABELS ABOVE